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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/147,490 05/13/99 MENDELSON

F 016786/0215

EXAMINER

HM12/0907

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3000 K STREET NW SUITE 500  
PO BOX 25696  
WASHINGTON DC 20007-8696

TURNER, S

ART UNIT

PAPER NUMBER

1647

DATE MAILED:

09/07/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/147,490**

Applicant(s)

**Mendelsohn et al**

Examiner  
**Sharon L. Turner, Ph.D.**

Group Art Unit  
**1647**

☒ Responsive to communication(s) filed on 5-13-99

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-17 is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-17 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Notice to Comply with Sequence Requirements.

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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### **DETAILED ACTION**

1. Claims 1-17 are pending.
2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1, 4, 5 and 10, drawn to the first technical feature and first method of use of a neuroactive peptide, the method drawn to modulating neuronal activity.

Group II, claim 2 and 3, drawn to the second technical feature and first method of use of a non-peptide analogue and peptidomimetic, the method drawn to modulating neuronal activity.

Group III, claims 6 and 9 drawn to the second method of treatment using the first technical feature.

Group IV, claims 7 and 8, drawn to the second method of treatment using the second technical feature.

Group V, claim 11, drawn to a method of screening by testing the ability of a compound to stimulate or inhibit the effect of LVV-haemorphin-7 on biological activity.

Group VI, claims 12 and 17, drawn to an antagonist of LLV-haemorphin-7 and pharmaceutical composition.

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Group VII, claim 13 and 16, drawn to an agonist of LLV-haemorphin-7 and pharmaceutical composition.

Group VIII, claim 14, drawn to a method of modulating neuronal activity with an agonist.

Group IX, claim 15, drawn to a method of modulating neuronal activity with an antagonist.

3. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The neuroactive peptide is anticipated as set forth in the IPER and thus lacks unity. The neuroactive peptide, non-peptide analogue and peptidomimetic analog are composed of different structural components including peptides, organic and inorganic materials. The methods differ in steps, reagents, technical features and outcomes including methods of modulating neuronal activity and methods of treating diseases.

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

In group I, species of biological activity selected from the group consisting of A) modifying learning and facilitating memory retrieval, B) modifying behaviour and increase in stereotypy behaviour, C) vasoactive effects, dilation of cerebral arteries, and increase in renal

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blood flow, D) neurite modeling, E) alleviation of the effects of spinal cord injury, F) motor neuron activity, G) cholinergic neuron activity and H) neuronal development.

In group III, species of conditions consisting of A) dementia, B) Alzheimer's disease, C) neuro-degenerative disorders of cholinergic pathways, D) neuro-degenerative disorders of motor pathways, motor neuron disease, and motor peripheral neuropathies, E) neuro-degenerative disorders of sensory pathways and sensory peripheral neuropathies, F) brain injury, G) spinal cord injury resulting from trauma, H) spinal cord injury resulting from hypoxia, spinal cord injury resulting from vascular disease and alleviation of the effects of spinal cord injury, I) modifying learning and facilitating memory retrieval, J) modifying behaviour and increase in stereotypy behaviour, K) vasoactive effects, dilation of cerebral arteries, and increase in renal blood flow, and L) neurite modeling.

In group V, species of modifying biological activity selected from the group consisting of A) modifying learning and facilitating memory retrieval, B) modifying behaviour and increase in stereotypy behaviour, C) vasoactive effects, dilation of cerebral arteries, and increase in renal blood flow, D) neurite modeling, and E) alleviation of the effects of spinal cord injury.

Applicant is required, in reply to this action, to elect a single species for each of the designated groups to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. The claims are deemed to correspond to the species listed above in the following manner:

The following claim(s) are generic: Claims 1, 6, 9 and 11.

6. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The diseases differ in etiologies, symptoms and disorders. The neuronal and biological activities differ in cell types, location and functional determinants.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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9. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.  
September 5, 2000

*Patricia A. Duffy*  
**PATRICIA A. DUFFY**  
**PRIMARY EXAMINER**



UNITED STATES DEPARTMENT OF COMMERCE  
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**Please find below a communication from the EXAMINER in charge of this application**

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

APPLICANT IS GIVEN 30 days FROM THE DATE OF THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.F.R. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Turner whose telephone number is (703) 308-0056. If the examiner cannot be reached, inquiries can be directed to Supervisory Patent Examiner Gary Kunz whose telephone number is (703) 308-4623. The fax number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



**NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES**

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☐ 7. Other: There is no statement that the CRF and paper copy are the same

**Applicant Must Provide:**

- ☐ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

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